EXHIBIT W

Risk assessment TVT blue

No changes have been made to the product and its intended use, apart from the colour. The biocompatibility of this new variations has been evaluated (section 9) and it has been concluded that the product will have the same safety level as the existing product.

Also the clinical evaluation revealed no new risks (section 11)

The design validation shows that the new variation delivers the intended visibility.

As no new risks have been identified the original risk assessment for TVT clear is also valid for TVT blue.

J. Jofer 29.05.02

Anhang 4-02/3: Bewertung der Gefahrenarten (Risikoanalyse nach EN 1441)

Product: TVT **Projekt :** ***Design Review:*** X ***Prozeß FMEA:***

Prozeßschritt:

Hazard	Source	Exposition / potential consequence	Failure Mode	Probability of occurance	Risk Class	Applicable safety measure	Other hazards generated?	Risk Class	Assessment of remaining risk
1) Bioburden	Manufacturer	Longterm/ Serious	Failure	Rare	5	Manufacturing under GMP-conditions, Control of bioburden	No	1	negligible
2) Non-decomposable residues	Manufacturer	Longterm/ Serious	Failure	Rare	5	Washing of needle, Biocompatibility-testing	No	1	negligible
3) Pyrogenity	See 1								
4) Wrong composition of material	See 19g and h								
5) Systemic Toxicity	Manufacturer	Longterm / Serious	Failure	Rare	5	Biocompatibility-testing	No	1	negligible
6) Genotoxicity /Teratogenicity	See5								
7) Allergical Effects	See5								
8) Cytotoxicity	See5								
9) Other bio-incompatibilities	n.a.								
10) Non-obedience of hygiene	User	Long / Serious	Failure	occasional	6	No special measures, as risk is not product specific			
11) (Cross-)Infection	n.a.								
12) Incompatibility with other devices or products	Use of former introducer version	Short / marginal	Failure	Frequent	1	Old version was retrieved from the customer. Customer information	No	0	acceptable
13) Lack of qualitative properties									
Treatment is not successfull	Not known	Long/ critical	Standard use	Probable	6	Patient-consent, less invasive than standard procedures	No	3	Risk accepted by patient
a) functional and qualitative properties									

a.a) no sufficient friction to maintain position even under stress without fixation	Manufacturer (wrong product / process)	Long / critical	Failure	Probable	5	Inspections at receiving, manufacturing and release of material / product	No	0	acceptable
	User (user does not remove the sheath)	Long / Critical	Failure	Probable	5	Package insert and training of users	No	0	acceptable
13.a.b) Complication rate higher than standard procedures	See 28 clinical risks								
13.a.c) Procedure cannot be performed under local or regional anesthesia (no cough-test possible)	Surgeon / patient	Long / Critical	Standard use	Rare	4	Cough-test required in package insert	No	I	negligible
13.a.d) No shorter recovery time	Conversion to open surgery	Long / critical	Standard use	Frequent	6	Patient-consent	No	3	Risk accepted by patient
13.a.e) Open surgery required	See 13.a.d)								
13a.f) Operating time higher than for standard procedure	Surgeon	Short / marginal	Standard use	Rare	0			0	acceptable
13.a.g) Needle curvature is not as required	Manufacturer	Short / serious	Failure	Occasional	6	Inspections at receiving, manufacturing and release of material / product	No	0	Acceptable
13.a.h) Needle tip is not as required (too sharp)	Manufacturer	Short / serious	Failure	Rare	5	Radius is specified, qualitative inspection at receiving	No	0	Acceptable
Needle tip is not as required (not as sharp as required)	Manufacturer	Short / serious	Failure	Rare	5	Radius is specified, qualitative inspection at receiving	No	0	Acceptable
13.a.i) Needle diameter is not as required	Not imaginable								
13.a.j) Needle end causes additional trauma	Not imaginable								
13.a.k) Needle too short	Manufacturer	Short / marginal	Failure	Remote	0		No	0	Acceptable

13.a.l) Needle does not allow the attachment of the introducer	Manufacturer / User	Short / moderate	Failure	Rare	1		No	1	Acceptable
13.a.m) Sheath does not glide easily	Not imaginable								
13 b) Treatment (not cuttable)	Not imaginable								
13 c) Mesh will be fixated	Surgeon	No hazard							
13 d) Mix-up (cannot be ditinguished from other products)	Not imaginable								
13 e) Not manageable with gloves	Not imaginable								
13 f) Not manageable with instruments	Not imaginable								
14) Human error/Reuse of disposable product	Not imaginable								
15) Insufficient warning of adverse reactions (only product related)	See 28 Clinical risks								
16) Loss of mechanical integrity	See 19 a and g								
17) Erroneous mechanical damage	Surgeon	No hazards							
18) Contamination as a result of waste –product and/ or waste of equipment	No special product related hazard								
19) Lack of quantitative properties									
a) Mechanical Properties a.a) needle									
a.a.a) Needle strength (needle breakage)	Manufacturer	Short / marginal	Failure	Frequent	1		No	1	Negligible
a.a.b) Needle bending (elastic deformation)	No hazard								

a.a.b) Needle bending (plastic deformation)	Surgeon	Short / marginal	Failure	Probable	0		No	0	Acceptable
a.a.c) Internal thread strength	Manufacturer	Short / marginal	Failure	Probable	0		No	0	Acceptable
a.a.d) Penetration resistance at urogenital diaphragma is too high	See 13 a.h								
a.b.) Mesh									
a.b.a) tensile strength	Manufacturer	Short / marginal	Failure	Probable	0		No	0	Acceptable
a.b.b) elongation	Manufacturer	Long / critical	Failure	Occasional	4	Inspection at receiving	No	0	Acceptable
a.b.c) bending stiffness	Manufacturer	Long / critical	Failure	Occasional	4	Inspection at receiving (Identity)	No	0	Acceptable
a.b.d) pore size	Manufacturer	Long / critical	Failure	Occasional	4	Inspection at receiving (Identity)	No	0	Acceptable
a.c) assembly									
a.c.a) push-off force	Manufacturer	Short / moderate	Failure	Frequent	3	Process validation according to defect class I	No	0	Acceptable
b) Dimesions									
b.a) needle									
b.a.a.(below min. diameter at shoulder)	Manufacturer	Short / critical	Failure	Remote	2	Inspection at receiving	No	0	Acceptable
b.b) mesh									
b.b.a) too short	Manufacturer	Short / moderate	Failure	Remote	2	Inspection during manufacturing	No	0	Acceptable
b.b.b) too small	Manufacturer	Long / critical	Failure	Rare	3	Inspection during manufacturing	No	0	Acceptable
b.c) sheath (too short)	Manufacturer	Short / marginal	Failure	Probale	0	Inspection during manufacturing	No	0	Acceptaable
b.d) shrink tube	See 19.a.c.a								
c) colour / appearence									
c.a) needle	Not imaginable								
c.b) mesh	Not imaginable								
c.c) sheath	See 19.a.c.a								
c.d) shrink tube	Not imaginable								
d) tightness	n.a.								
e) strength of mesh (vivo / vitro)	Not imaginable								
f) absorption	n.a								
g) Composition									
g.a) needle	See 19.a.a.a								

g.a.a (needle breakage)	See 19.a.a.a								
g.a.b (biocompatibility)	Manufacturer	short / serious	Failure	Incredible	2	Inspection at receiving (Identity)	No	0	Acceptable
g.b) mesh	Not imaginable								
g.c) sheath	See 19.b.c								
g.d) shrink tube	See 19.a.c.a								
h.) construction									
h.a) mesh	See 13.a.a								
h.b) attachment	See19.a.c.a								
h.c) transition	See 19.a.c.a								
20) Missing adequate determination when the usability of the product expires	Not imaginable								
21) Insufficient Packaging **a)** Contamination of the product or user	Manufacturer	Long / serious	Failure Mode						
b) Decline of equipment/device condition									
22) Discharge of liquids	Not applicable								
23) Magnetic Fields	Not applicable								
24) Electrocauter									
25) Moisture Storage/Transport									
26) Air pressure Storage/Transport									
27) Temperature Storage/Transport									
28) Clinical Risks									
a) Intraoperative bladder perforation	User	Long / critical	Failure Mode	Probable	5	-Info in IFU (Diagnostic by Cystoscopy) and Training of User	No	0	acceptable

b) Intraoperative blood loss exceeding 300 ml blood coagulation dissorder or injury of minor vessels)	User	long / moderate	Failure Mode	Rare	4	Patient monitoring is standard procedure	No	0	acceptable
c) Overtensioning of tape	User	Long / critical	Failure Mode	Probable	5	-Info in IFU -Training	No	0	Acceptable
d) Level of wound infection and urinary tract infection higher than for other incontinence procedures	Not imaginable								
e) Injury of major vessels	User	Short / serious	Failure Mode	Frequent	7	-Info in IFU -Training -Restricted marketing (only to customers , equiped to be able to treat the injury - During the training it must be emphazized that the procedure should only be performed if a quick access to an intensive care unit is available	No	1	negligible
f) Injury of nerves	User	long / serious.	Failure Mode	Ocassional	6	-Info in IFU -Training	No	1	negligible
g) Injury of bowel	User	Short / serious	Failure Mode	Occasional	6	-Info in IFU -Training	No	1	Negligible
h) Injury of urethra	User	Short / critical	Failure Mode	Frequent	3	- Info in IFU - Training	No	0	Acceptable
i) Bladder perforation	User	Short / critical	Failure Mode	Frequent	3	- Info in IFU - Training	No	0	Acceptable
j) Prolonged urinary retention	See 28c								
k) De novo detrusor instability	User	Long / critical	Failure Mode	Occasional	4	- Info in IFU - Training	No	0	Acceptable
l) Postoperative erosion of urethra	User	Long / critical	Failure Mode	Occasional	4	- Info in IFU - Training	No	0	Acceptable

m) Postoperative erosion of bladder	Standard procedure	Long/ critical	Standard-use	Incredible	2		No	2	Acceptable as clinically not observed
n) Postoperative erosion of vagina	Delayed healing caused by: Patient or surgeon	Long / moderate	Failure Mode	Occasional	4	Surgeon : Info in IFU Training	No	0	Acceptable as it is equivalent to standard procedures and not product specific
o) Haematoma which needs treatment (removal)	Procedure related	Long / critical	Standard use	Incredible	2	Patient-consent, less invasive than standard procedures	No	2	General risk for invasive procedures. Risk accepted by patient
) Haematoma which needs treatment (removal)	Surgeon	Long / critical	Failure Mode	Improbable	3	Patient-consent, less invasive than standard procedures	No	3	General risk for invasive procedures. Risk accepted by patient
29) Others									

Is safety of product adequate ? Yes ☒ No ☐ Further measures:.....

Carried out by: J. Höfer Date: 08.05.01 Reviewed by:..... Reg. Aff.

Scientific Director 8.5.01 Marketing Manger

Medical Affairs B. Hellmann / 8.5.01 Proj. L. Scient. Aff. C. Wiecker / 14.05.01

m) Postoperative erosion of bladder	Standard procedure	Long/ critical	Standard-use	Incredible	2		No	2	Acceptable as clinically not observed
n) Postoperative erosion of vagina	Delayed healing caused by: Patient or surgeon	Long / moderate	Failure Mode	Occasional	4	Surgeon : Info in IFU Training	No	0	Acceptable as it is equivalent to standard procedures and not product specific
o) Haematoma which needs treatment (removal)	Procedure related	Long / critical	Standard use	Incredible	2	Patient-consent, less invasive than standard procedures	No	2	General risk for invasive procedures. Risk accepted by patient
) Haematoma which needs treatment (removal)	Surgeon	Long / critical	Failure Mode	Improbable	3	Patient-consent, less invasive than standard procedures	No	3	General risk for invasive procedures. Risk accepted by patient
29) Others									

Is safety of product adequate ? Yes ☒ No ☐ Further measures:.....

Carried out by: T. Hofer..... Date: 08.05.01 Reviewed by:.....

Reg. Aff.

Scientific Director 8.5.01 Marketing Manger 31/05/01

Medical Affairs B. Hellmanns / 8.5.01 Proj. L. Scient. Aff. C. Lucio Kgl / 14.05.01

ETHICON SARL

QA Memo

To: .Technical File

From: Agnès SIFFERLEN

CC:

Date: July 26, 2000

Subject: RISK ANALYSIS

Re: QAMemo1700

The original risk analysis for TVT implant and introducer written by Medscan is still valid (see risk analysis rev 7 dated February 6, 2000).

An additional analysis was done to document the packaging change. (see Device design safety assement summary report rev 0)

Agnès SIFFERLEN

Quality System and compliance supervisor.

PREVENTIA

TVT-2

Product:	Artkel No:
TVT-2 needles, introducer	TVT-2
Customer:	Responsible:
	ME / TS
Prepared:	Revision date:
1998-09-22	2008-02-06
Revision No:	
7	
Approved by:	
Preventia AB, Dep Education / 0256-1	

PREVENTIA

TVT-2

Reg No: MED-91 Eng	Artikl No: TVT-2	Product: TVT-2 needles, introducer
Note: Treatment of SUI	Drawing No: P15113, P15111, P15112	Dept: QA
Customer:	Responsible: ME / TS	Prepared: 1998-09-22
Revision No: 7	Revision date: 2000-02-06	Page: 1 of 1

Note

Analysis made 1998-09-22 by Margareta Eriksson and Tommy Svensson (PREVENTIA AB).
System description, see attached drawings.

Review of analysis 1999-01-27 by Margareta Eriksson and Tommy Svensson (PREVENTIA AB).
The revised TVT-2 device:
5 mm needle
Shiny surface
Tip angle same as 6 mm
Transparent shrink tube
Packed in double plastic
Handle screw instead of o-ring

Utgåva 4 1999-06-01
Genomgång av ME / TS

Utgåva 5 1999-06-23
Ny värdering av risker TS / ME

Issue 6
Review of risk analysis based surveillance data and complaint statistics 1999.
Performed by ME and TS 2000-02-02.

Issue 7
Revision ov text and Risknumbers after action taken (typing errors)

PREVENTIA

TVT-2

Reg No: MED-91 Eng	Artikl No: TVT-2	Product: TVT-2 needles, introducer
Note: Treatment of SUI	Drawing No: P15183, P15181, P15182	Dept: QA
Customer:	Responsible: ME / TS	Prepared: 1998-09-22
Revision No: 7	Revision date: 2000-02-06	Page: 1 of 1

Scales

RPN = Po*S *Pd

Po, Prob of occur.
1 Not likely, <1:100 000
2 Very low probability, <1:50 000
3 Very low probability, <1:10 000
4 Low probability, <1:5 000
5 Low probability, <1:1 000
6 Medium probability <1:500
7 Medium probability, <1:100
8 High probability, <1:50
9 High probability, <1:10
10 Very high probability, 1:1

S, Severity
1 No effect
2 Limited effect on function or appearance
3 Limited effect on function or appearance
4 Severe effect on function or appearance
5 Minor reversible injury, no function
6 Minor reversible injury, no function
7 Severe reversible injury, small irreversible injury
8 Minor irreversible injury
9 Severe irreversible injury
10 Death

Pd, Prob of detec.
1 Will always be discovered
2 Very high probability of detection
3 High probability
4 Normal probability
5 Minor probability
6 Minor probability
7 Low probability
8 Low probability
9 Will probably not be detected
10 Will not be detected

PREVENTIA

TVT-2

Reg No: MED-91 Reg	Artikel No: TVT-2	Product: TVT-2 needles, introducer
Note: Treatment of SUI	Drawing No: P15113, P15111, P15112	Dept: QA
Customer:	Responsible: ME / TS	Prepared: 1998-09-22
Revision No: 7	Revision date: 2000-02-06	Page: 1 of 6

Process step:	Failure mode	Cause	Effect	Control	Po	S	Pd	RPN	Action/follow-up	.	Responsi-	P-	S	P-	RPN
(5) Preparing for the surgical procedure	Unsterile Introducer	Sterilisation (on site) has not been effective	Surgeons gloves unsterile -> risk for infection	Instruction from MMAB concerning cleaning and sterilisation	1	6	2	12*	Acceptable risk	x		1	6	2	12*
	Unsterile TVT-2 device (single use)	Sterilisation process not effective	Infection	MMAB EN 46 001, sterilization validation performed	1	8	2	16*	Acceptable risk	x		1	8	2	16*
		Sterile package not effective	Infection	MMAB EN 46 001, sterile package validation performed	1	8	2	16*	Acceptable risk	x		1	8	2	16*
	Damaged TVT-2 device	Unearefal handling during manufacture / transport / preparation	Tissue damage or new treatment	No pre-caution in instruction manual concerning damage during preparation.	1	5	2	10*	Acceptable risk	x		1	5	2	10*
		Needle falls outside the instrument table, tape stretched, protective sheath overlay separated	Tissue damage or new treatment	Normal preparation techniques in operating theater	1	5	2	10*	Acceptable risk	x		1	5	2	10*
		Protective caps falling off, needle tips damaged	Tissue damage or new treatment	The angle of the needle tip is same as 6 mm design. Protective caps.	1	5	2	10*	Acceptable risk.	x		1	5	2	10*
	Wrong size of TVT device	Mislabelling of package / wrong shipment / wrong device prepared by nurse	The handle will not fit / treatment not possible	MMAB Quality system. 5 mm resp 6 mm needles have different article nos.	1	4	1	4	Acceptable risk	x		1	4	1	4

* = Risk of injury

PREVENTIA

TVT-2

Reg No: MED-91 Eng	Artiel No: TVT-2	Producth: TVT-2 needles, introducer
Notat: Treatment of SUI	Drawing No: P15113, P15111, P15112	Dept: QA
Customer:	Responsible: ME / TB	Prepared: 1998-09-22
Revision No: 7	Revision date: 2008-02-06	Page: 2 of 6

Process steg	Failure mode	Cause	Effect	Control	Fo	S	Fd	RPN	Action/follow-up	-	Responsi-	P-	S	P-	RPN
(2) Attaching Introducer to the needle	Introducer loose from TVT-2 device	Screw not assembled correct in handle	Screw drops on the floor -> unsterile. New introducer must be prepared, delayed procedure.	Instr. for use describes procedure for introducer assembly after cleaning and sterilization	1	5	1	5*	Acceptable risk	x		1	5	1	5*
		6 mm Introducer attached to 5 mm TVT-2 device needle	New Introducer must be prepared, delayed procedure	Not possible	1	1	1	1	Acceptable risk	x		1	1	1	1
		Screw threading on handle worn out	Screw drops on the floor -> unsterile. New Introducer must be prepared, delayed procedure	Assembly procedure in Instructions for use. Screw thread length increased.	1	5	1	5*	Acceptable risk	x		1	5	1	5*
	Needle / Introducer attachment unstable	Screw not enough fixed	Unstable needle tip position, unintentional tissue damage (incl. Uretra).		1	8	1	8*	Acceptable risk.	x		1	8	1	8*
		The screw slightly reversed (unwound) by the surgeons hand during procedure	Unstable needle tip position, unintentional tissue damage (incl. Uretra).		1	8	1	8*	Acceptable risk	x		1	8	1	8*
	Tape and protective sheath clamped between Introducer and Needle	Wrong assembly procedure by nurse / surgeon	Sheath separates. Damage to tissue due to damaged tape. New procedure required.	1999-06-01: 20800 operations performed to date, no reports concerning this failure mode.	2	5	2	20*	Acceptable risk.	x	ME	2	5	2	20*

* = Risk of injury

PREVENTIA

TVT-2

Reg No: MED-91 Eng	Artkl No: TVT-2	Product: TVT-2 needles, introducer
Note: Treatment of SUI	Drawing No: P15113, P15111, P15112	Dept: QA
Customer:	Responsible: ME / TS	Prepared: 1998-09-22
Revision No: 7	Revision date: 2000-02-06	Page: 3 of 6

Process step:	Failure mode	Cause	Effect	Control	Po	S	Pd	RPN	Action/follow-up	.	Responsi-	P-	S	P-	RPN
	Needle does not fit to introducer	Dimensions of Needle resp. Introducer wrong.	Needle not possible to fix to Introducer, Introducer sticks to Needle. New procedeure	Manufacturing of Needle validated	1	4	1	4	Acceptable risk.	x		1	4	1	4
(3) Penetration of tissue / surface of abdomen	Penetration of bladder	Anatomy is such that it may happen	Patient catheter 1 / 3 days.	Cystoscope in bladder during procedure. Instruction available in surgical procedure	8	5	2	80*	Acceptable risk. See litterature review.			8	5	2	80*
	Penetration of Urethral wall	Damage by needle tip during insertion	Urethral wall damaged, leakage, scar on Urefara	Instructions to use catheter guide.	3	8	6	144*	Acceptable risk.			3	8	6	144*
	Bleeding from pelvic floor / space of Rezius	Anatomy is such that it may happen	Bleeding in the tissue	Instructions for use, surgical procedure. Surgeon must be familiar with SUI procedure	7	7	2	98*	Acceptable risk			7	7	2	98*
		TVT instrument unstable	Bleeding in the tissue	Instructions for use, surgical procedure.	1	7	2	14*	Acceptable risk.			1	7	2	14*
	Lateral vascular injury	Wrong surgical technique.	Bleeding in the tissue	Instructions for use, surgical procedure. Surgeon must be familiar with SUI procedure	3	9	2	54*	Acceptable risk. Change instructions for use to include needle position in patient length direction			3	9	2	54*
		TVT instrument unstable	Bleeding in the tissue	Instructions for use, surgical procedure.	1	9	2	18*	Postmarket surveillance.		ME	1	9	2	18*
	Damage to nerves, local anestesia	Anatomy is such that it may happen	Damage to nerve functions, pain	Instructions for use, surgical procedure	2	8	2	32*	Acceptable risk	x		2	8	2	32*

* = Risk of injury

PREVENTIA

TVT-2

Reg No: MED-91 Eng	Artikl No: TVT-2	Product: TVT-2 needles, introducer
Note: Treatment of SUI	Drawing No: P15113, P15111, P15112	Dept: QA
Customer:	Responsible: ME / TS	Prepared: 1998-09-22
Revision No: 7	Revision date: 2009-02-06	Page: 4 of 6

Process step:	Failure mode	Cause	Effect	Control	Po	S	Pd	RPN	Action/follow-up	-	Responsi-	P-	S	P-	RPN
	Damage to nerves, spinal epidural general anestesia	Anatomy is such that it may happen	Damage to nerve functions, postoperative pain	No pain, more difficult	2	8	6	96*	Acceptable risk	x		2	8	6	96*
	Bowl perforation / obstruction	Wrong surgical procedure, anathomy is such that it may happend	Pain, peritonitis		2	9	4	72*	Acceptable risk.	x		2	9	4	72*
	Needle torsion resistance too low	Diameter of needle 5 mm instead of 6 mm	Uncontrolled Needle tip position, unintentional tissue damage (incl Uretra).	Specification of tensile strength and torsion strength available in supplier certificate.	1	8	2	16*	Acceptable risk.	x		1	8	2	16*
	Radius of Needle wrong	Wrong manufacturing	Uncontrolled Needle tip position. Unintentional tissue damage incl. Uretra		1	8	4	32*	Acceptable risk	x	ME	1	8	4	32*
	Needle broken during procedure	Insufficient mechanical strength of Needle	Rests of the needle removed (surgical intervention).		6	5	1	30*	New needle design / material (2333) <2009-03-01		ME	6	5	1	30*
	Protective sheath overlap separated	Wrong assembly	Damage to the prolene mesh, damage to tissue, new procedure	MMAB Quality system	2	5	2	20*	Acceptable risk	x		2	5	2	20*
		Accidental separation of overlap during surgical procedure	Damage to the prolene mesh, repeat the procedure	Surgeons attention	2	5	2	20*	Acceptable risk	x		2	5	2	20*
	Needle resistance to tissue lower compared to 6 mm TVT sandblastered Needle	Smaller diameter compared to 6 mm	Less control of pos. of Needle tip during surg. procedure.		2	8	2	32*	Acceptable risk	x	ME	2	8	2	32*

* = Risk of injury

PREVENTIA

TVT-2

Reg No: MED-91 Eng	Artel No: TVT-2	Product: TVT-2 needles, introducer
Note: Treatment of SUI	Drawing No: P15113, P15111, P15112	Dept: QA
Customer:	Responsible: ME / TS	Prepared: 1998-09-22
Revision No: 7	Revision date: 2000-02-06	Page: 5 of 6

Process step:	Failure mode	Cause	Effect	Control	Po	S	Pd	RPN	Action/follow-up	.	Responsi-	P-	S	P-	RPN
	Tape and protective sheath separates from Needle	Force of MT 5000 clear attachment (shrink tube) less compared to TVT generation I	New treatment, protective sheath remains in tissue, removed surgically		1	5	1	10*	Acceptable risk.	x	ME	1	5	2	10*
	Toxicological reaction	Toxic material in clear attachment (shrink tube) Altera MT-5000 (clear)	Shock, sensibilization	Toxicological testing results of Raychem material available Altera MT-5000 (clear)	1	8	2	16*	Acceptable risk	x		1	8	2	16*
		Toxic material in protective sheath	Shock, sensibilization	Toxicological data available	1	8	2	16*	Acceptable risk	x		1	8	2	16*
		Toxic material in Prolene tape	Shock, sensibilization	Toxicological test results available	1	8	2	16*	Acceptable risk	x		1	8	2	16*
(4) Removal and re-introduction of needle (in case of bladder penetration)	No risks identified.														
(5) Release of introducer from Needle	Needle does not separate from Introducer	Dimensions of Needle resp. Introducer wrong.	Excess force required to remove Needle. New procedeure.	Validation of manufacturing of Needles.	2	4	2	16*	Acceptable risk.	x		2	4	2	16*
(6) Bringing the needle above the abdominal wall	Protective sheath loosens from mesh and/or mesh loosens before it is cut	Insufficient tensile strength below the protective sheath	Remove the protective sheath through surgical procedure. Repeat the procedure		2	6	2	24*	Acceptable risk.	x		2	6	2	24*
(7) Repeat on the other side	No specific risks identified														
(8) Cutting tapes and remove needles	Tape and protective sheath slips below abdominal wall surface	Tape too short / woman too obese	Try to locate tape end, new procedure, alternative treatment	Instructions for use clear.	2	4	2	16	Acceptable risk	x		2	4	2	16

* = Risk of injury

PREVENTIA

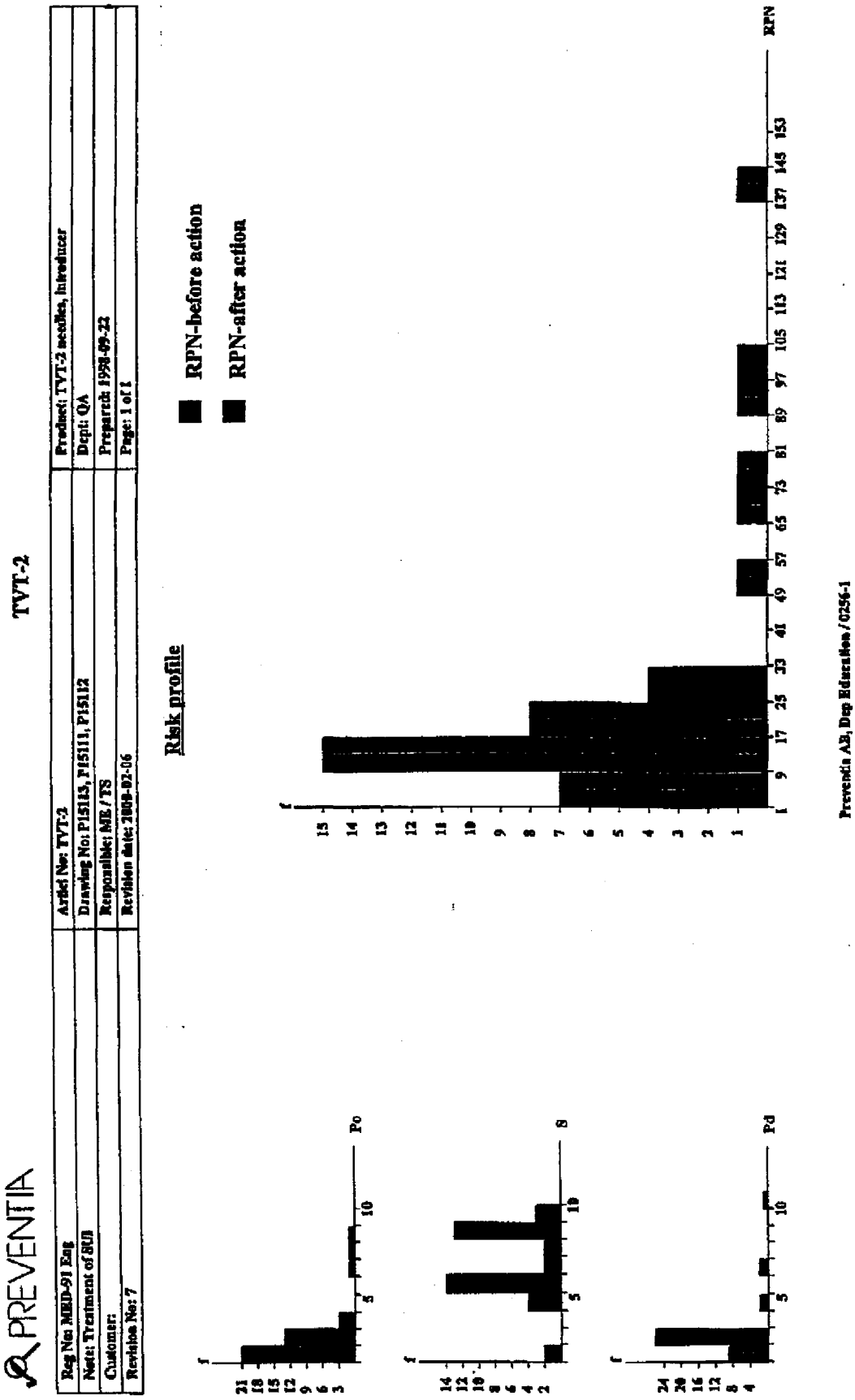
TVT-2

Reg No: MED-91 Eng	Artikel No: TVT-2	Product: TVT-2 needles, introducer	
Note: Treatment of Stiff	Drawing No: P15113, P15111, P15112	Dept: QA	
Customer:	Responsible: ME / TS	Prepared: 1998-09-22	
Revision No: 7	Revision date: 2000-02-06	Page: 6 of 6	

Process step:	Failure mode	Cause	Effect	Control	Po	S	Pd	RPN	Action/follow-up	-	Responsi-	P-	S	P-	RPN
(9) Tension adjustment and cough-test	Too hard tension	Wrong judgement by surgeon	Urine retention, resident urine, repeat the procedure, loosen the mesh	Instructions for use clear.	2	5	2	20*	Acceptable risk.	x		2	5	2	20*
	Too loose tension	Wrong judgement by surgeon	No treatment effect (leakage). New procedure.	Instructions clear.	2	5	2	20*	Acceptable risk	x		2	5	2	20*
(10) Removal of the protective sheath	Difficult to remove	Friction in overlap	Remove the protective sheath by other means, delay of procedure		3	5	1	15*	Acceptable risk	x		3	5	1	15*
	Particles from Prolene mesh falls off into the tissue	Tape edges damaged	No effect. Implantable material.		2	1	10	20	Acceptable risk.	x		2	1	1-0	20
(11) Cutting of the tape under the skin, suturing the incisions	No risks identified														
(12) End of procedure	No risks identified														

* = Risk of injury

Preventia AB, Dep Education / 0256-1


PREVENTIA
TVT-2
Reg No: MED-91 Eng
Note: Treatment of SUI
Customer:
Revision No: 7
Artikel No: TVT-2
Drawing No: P15113, P15111, P15112
Responsible: ME / TS
Revision date: 2009-02-06
Product: TVT-2 needles, introducer
Dept: QA
Prepared: 1998-09-22
Page: 1 of 1
Risk profile
RPN-before action
RPN-after action
RPN
Po
S
Pd
Preventia AB, Dep Education / 0256-1